DEPARTMENT OF HEALTH & HUMAN SERVICES

94713d

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 12, 2004 W/L: 38-04

Joseph V. Hernandez, President
World Variety Produce, Inc.
5325 South Soto Street
Vernon, CA 90058

Dear Mr. Hernandez:

The Food and Drug Administration (FDA) has analyzed the contents of and reviewed the label for your product Melissa's Dried Cranberries, 3 oz. retail packages. An FDA investigator collected a sample of the dried cranberry product during an inspection at your firm conducted on December 30 & 31, 2003. FDA analyzed the Vitamin C content and compared the results to the amount declared on the label of your product.

Your product, Melissas's Dried Cranberries, 3 oz. retail package, is misbranded under section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 343(a)(1)) in that the labeling is false or misleading. Your label states that the product contains 20% of the daily value of Vitamin C. However, our laboratory analysis found the product to contain 0.06% and 0.206% (original and check analysis respectively) of the daily reference intake (RDI) of Vitamin C. A food is deemed to be misbranded under 21 CFR 101.9(g)(4)(ii) if the level of a naturally occurring nutrient in a food is less than 80% of the value for that nutrient declared on the label. You can find the Act and its implementing regulations through links included in FDA's home page at www.fda.gov.

The above violation is not meant to be an all-inclusive list of deficiencies concerning your labels or products. It is your responsibility to ensure that all of your products are labeled in compliance with the Act and FDA's regulations. You should take prompt action to correct this violation and to prevent its future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible regulatory actions include seizure and/or injunction.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct this violation. You may wish to include in your response revised labels or copies of other useful information that

would assist us in evaluating your corrections. If you cannot complete all of the corrections before you respond, your response should explain the reason for your delay and state when you will correct any remaining violations.

Your written reply should be addressed to:

Director, Compliance Branch
U.S. Food and Drug Administration
19701 Fairchild
Irvine, California 92612-2445

If you have any specific questions regarding this letter, please contact Robert McNab, Compliance Officer, at (949) 608-4409.

Sincerely,

Alonza E. Cruse
District Director